INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32547]

Kansas City Southern Railway Company—Construction and Operation Exemption—to Exxon Corporation's Plastics Plant Near Baton Rouge and Baker, LA

AGENCY: Interstate Commerce Commission.

ACTION: Notice of conditional exemption.

SUMMARY: Under 49 U.S.C. 10505, the Commission exempts from the prior approval requirements of 49 U.S.C. 10901 Kansas City Southern Railway Company's (KCS) construction and operation of a line of railroad. The proposed line would be about .375 miles long, beginning at KCS milepost 40 + 07.2 on the KCS Stupp lead, located near the intersection of U.S. Highway 61 and Thomas Road (LA Hwy 423), near Baker, LA, and connecting with the industry track facilities of the Exxon Corporation's Baton Rouge Plastics Plant located south of Thomas Road (LA Hwy 423) near Baker, LA. (milepost 17 + 99.8 of the Stupp lead).

DATES: Petitions to reopen must be filed by November 28, 1995.

ADDRESSES: Send pleadings referring to Finance Docket No. 32547 to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, 1201 Constitution Avenue, N.W., Washington, DC 20423; and (2) Petitioner's representative: John R. Molm, Troutman Sanders, 601 Pennsylvania Avenue, N.W., Suite 640, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 927–5660. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: DC NEWS & DATA, INC., Interstate Commerce Commission Building, 1201 Constitution Avenue, N.W., Room 2229, Washington, DC 20423. Telephone: (202) 289–4357/4359.

Decided: October 30, 1995.

By the Commission, Chairman Morgan, Vice Chairman Owen, and Commissioner Simmons.

Vernon A. Williams,

Secretary.

[FR Doc. 95–27677 Filed 11–7–95; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 22, 1995, Hoffmann-LaRoche, Inc., 340 Kingsland Street, Nutley, New Jersey 07110, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the Schedule II controlled substance levorphanol (9220).

The firm plans to manufacture finished dosage forms for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the above application.

Any such comments or objections may be addressed to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than January 8, 1996.

Dated: October 24, 1995.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 95–27675 Filed 11–7–95; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 94–27]

Hugh I. Schade, M.D.; Denial of Application

On February 25, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Hugh I. Schade, M.D., (Respondent) of San Jose, California, notifying him of an opportunity to show cause as to why DEA should not deny his pending application, executed on August 28, 1992, for registration as a practitioner under 21 U.S.C. 823(f), as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged that: (1) In September and October 1987 a DEA inspection of the Respondent's registered location revealed discrepancies in his recordkeeping and security, including the storage of controlled substances at an unregistered location, and an audit revealed overages and shortages of controlled substances, including a shortage of 4,193 dosage units of Diazepam, a Schedule IV controlled substance; (2) during the DEA audit, the Respondent and his wife admitted to personally using acetaminophen with codeine products and Anexsia, a Schedule III controlled substance, out of office stock, since 1985, without recording the usage; (3) on September 12, 1989, the Respondent was arrested on thirty-one counts of violating the California Health and Safety Code by prescribing controlled substances without a legitimate medical purpose and not in the usual course of professional practice; (4) on December 18, 1991, the Respondent was convicted in the Superior Court of California, Santa Clara County, of thirteen felony counts of issuing controlled substance prescriptions without medical cause and one count of manslaughter, arising out of a patient's drug overdose death.

On March 1, 1994, the Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in San Francisco, California, on October 26 and 27, 1994, before Administrative Law Judge Paul A. Tenney. At the hearing, both parties called witnesses to testify and introduced documentary evidence, and after the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. On January 12, 1995, Judge Tenney issued his Findings of Fact, Conclusions of Law, and Recommended Ruling, recommending that the Respondent's application for registration be denied, and also writing that ''the Respondent is encouraged to reapply in about one year from the effective date of any final decision in this case.'' Neither party filed exceptions to his decision, and on February 15, 1995, Judge Tenney transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, and his adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that the parties have stipulated to the following: (1) That Anexsia, a brand name for a product containing hydrocodone, is a Schedule III narcotic

controlled substance pursuant to 21 CFR 1308.13(e); (2) that codeine is a Schedule III narcotic controlled substance pursuant to 21 CFR 1308.13(e); (3) that Tylenol No. 3, Tylenol No. 4, and Empirin with codeine, brand names for products containing codeine, are Schedule III narcotic controlled substances pursuant to 21 CFR 1308.13(e); and (4) that Diazepam is a Schedule IV narcotic controlled substance pursuant to 21 CFR 1308.14(c).

In October 1986, an investigation was opened by the DEA after a Diversion Investigator received information that the Respondent had purchased controlled substances containing codeine and dihydrocodeinone in quantities in excess of average U.S. and California practitioners. An administrative inspection warrant was served on the Respondent's Los Gatos Boulevard location in September 1987. Prior to serving the warrant, the investigators determined that the Respondent had only one valid DEA registration, which was for his Los Gatos Boulevard office. However, investigators discovered that the Respondent was storing controlled substances at unregistered locations, to include his medical office on Crown Boulevard in San Jose, and his Almaden Valley residence. The investigators also discovered that the Respondent had failed to take a beginning inventory, to conduct a biennial inventory, and to properly complete DEA Form 222 for Schedule II controlled substances.

An audit was conducted, and the Respondent was unable to account for approximately 3,000 dosage units of acetaminophen with codeine. Although he maintained that he did not know what happened to these dosage units, the Respondent admitted to the investigator that he and his wife had personally used this substance out of office stock without recording the usage. There were also overages and shortages of other controlled substances. Police reports reflected that in late 1983 and early 1984, controlled substances were stolen from the Respondent's office, but such thefts had not been reported to DEA, as required. However, the Respondent had a theft and loss of controlled substances in 1976 and reported that loss to both the local police and the DEA. Also, he testified that he was aware of the requirement to report such incidents to the DEA.

The investigators also examined the physical security provided for the storage of controlled substances, noting that the storage room door was left ajar more than once, and since no staff members controlled access to the area, patients could enter and leave the room undetected. Investigators also learned from the Respondent that storage cabinets containing controlled substances were accessible to drug company representatives as well as patients, without staff supervision.

Following the investigation, the Respondent was charged and convicted in a California Superior Court of involuntary manslaughter and 13 counts of unlawfully prescribing controlled substances. The Respondent appealed the conviction, and the appellate court affirmed the involuntary manslaughter conviction, and, with one judge dissenting, reversed the conviction for unlawfully prescribing controlled substances, finding that the trial court's failure to instruct *sua sponte* on the definition of the term ''addict'' was reversible error. See *People* versus *Schade*, 25 Cal. App. 4th 1605 (Cal. Ct. App. 1994).

The manslaughter conviction stemmed from the Respondent's treatment of John Barker from December 11, 1985, until his suicide by means of an overdose of Tylenol and Darvon on September 17, 1987. The Report of the Respondent's Probation Officer, made of record, contained factual details concerning the manslaughter conviction. Specifically, in treating Mr. Barker, the Respondent prescribed codeine and depressants such as Restoril, Soridol, Soma, and Ativan. On September 9, 1986, the Respondent began prescribing Darvon or Darvocet to Mr. Barker, as well as Dalmane and Halcion. The Physicians' Desk Reference indicates a warning that Darvon should be prescribed with caution when the patient is also taking tranquilizers such as Halcion, Restoril, or Ativan.

On August 21, 1987, Mr. Barker was hospitalized after a suicide attempt in which he took an overdose of multiple medications. The Respondent noted on Mr. Barker's record on August 24, 1987, that he was extremely depressed and had stated that he did intend to take his own life. On September 3, 1987, the Respondent prescribed a depressant, Xanax, and on September 11, 1987, the Respondent prescribed 100 tablets of Darvocet. After Mr. Barker's suicide attempt, relatives confronted the Respondent regarding the prescribed medications and their fear that Mr. Barker again would attempt suicide. The relatives were also concerned that the Respondent had released Mr. Barker too soon after his admission for the suicide attempt, for he was released from the hospital in less than 24 hours after his admission. On September 17, 1987, Mr. Barker was found in his car with the engine running, and the initial impression of the coroner was death by carbon monoxide poisoning. However, results of an autopsy indicated a blood-alcohol level of 0.13 percent and toxic levels of Darvocet, while his carbon monoxide level was a low two percent.

At the trial, Dr. Drottar, an emergency room physician, testified, among other observations, that the Respondent's dispensing of 100 Darvocet tablets three days after a serious suicide attempt was criminal negligence. Psychiatrist Dr. Keins, who evaluated Mr. Barker at the Emergency Psychiatric Services on September 4, 1987, testified that giving Mr. Barker 100 Darvocet tablets at that time would be ''like handing him a loaded gun,'' given his mental status and his depression.

At the hearing before Judge Tenney, the Respondent testified that he had given no specific warnings to Mr. Barker concerning the use of Darvocet with alcohol. He also testified that at the time of his last visit with Mr. Barker, he did not seem depressed and was not threatening suicide. However, the Respondent also testified that, at that time, he did not know about the earlier emergency room overdose treatment.

The Respondent has practiced medicine since 1962 and has a current California license to practice medicine. There are no current actions pending against him before the Medical Board of California. Several of the Respondent's patients testified on his behalf, recounting their friendship with him and his skill as a physician. The Respondent also testified, stating the corrective actions taken after DEA investigators informed him of the need for a DEA Certificate of Registration for each location where he dispensed controlled substances.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration if he determines that such registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether an application for registration should be denied. See Henry J. Schwarz, Jr., M.D., Docket No. 88–42, 54 FR 16422 (1989).

In this case, all five factors are relevant. As to factor one, the Respondent has a current California license to practice medicine, and there are no current actions pending before the State medical board. Regarding factors two, ''experience in dispensing * * * controlled substances,'' and four, ''compliance with applicable State, Federal, or local laws,'' 21 U.S.C. 827(a)(3) and 21 CFR 1304.21 and 1304.24 require a registrant who dispenses a controlled substance to maintain a current, complete, and accurate record of every such dispensing of the substance. Also sections 1304.11 to 1304.13, and 1305.06 of the Code of Federal Regulations establish requirements for inventory procedures and for completing DEA Form 222. Yet, the record contains evidence that the Respondent failed to conduct required inventories, was unable to account for about 3,000 dosage units of acetaminophen with codeine, incurred other shortages and overages of controlled substances relegated to his care, and failed to completely and accurately fill out the DEA Form 222. Additionally, both the Respondent and his wife personally used acetaminophen with codeine out of the office supply without recording their personal usage. Such disregard of recordkeeping requirements exemplify the basis for concern about potential diversion of controlled substances resulting from such improper accountability; concerns properly addressed under factors two and four.

Also, 21 CFR 1301.23 requires a separate registration for each location in which controlled substances are to be dispensed, and 21 CFR 1301.71 establish security requirements. Yet the Respondent stored controlled substances at his Crown Boulevard location and at his home, despite the lack of a valid DEA registration for either of those locations. Such actions demonstrate a disregard for these regulatory requirements. Further, the lax security procedures resulting in patients and drug company representatives having access to drug storage areas further demonstrate a disregard for security regulations.

Finally, concerning factor five, the Respondent was convicted in State court of one count of involuntary manslaughter arising out of a patient's drug-overdose death in September 1987. The conviction was affirmed upon appeal. The Deputy Administrator assigns substantial weight to the pattern of behavior exhibited by the Respondent in his prescribing practices to this patient. The threat to the public health and safety of such practices directly impacts upon the public interest.

Although the Deputy Administrator has taken into account the length of time the Respondent has practiced medicine, the lack of prior convictions or adverse State board action, and the testimony of the Respondent's witnesses concerning his contribution to his community and their opinion of his professional care, he also notes the lack of any evidence which provides assurances that the Respondent's future practice will include closer monitoring of patient symptoms and treatment, as well as compliance with Federal and State laws and regulations concerning the dispensing and storage of controlled substances. Such lack of mitigating evidence, coupled with the severity of the circumstances surrounding the involuntary manslaughter death of Mr. Barker, result in a conclusion that the granting of the Respondent's application for a DEA Certificate of Registration at this time would be inconsistent with the ''public interest'' under 21 U.S.C. 823(f). Therefore, the Deputy Administrator finds that the public interest is best served by denying the Respondent's application for a DEA Certificate of Registration. If the Respondent reapplies and submits evidence showing corrective actions taken to bring his practice into conformance with DEA regulations, his application may receive more favorable consideration.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823, and 21 CFR 0.100(b) and 0.104, hereby orders that the Respondent's Application for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective December 8, 1995.

Dated: November 2, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–27676 Filed 11–7–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Office of the Secretary

Glass Ceiling Commission Open Meeting

SUMMARY: Pursuant to section 10(a) of FACA, this is to announce that the open teleconference meeting of the Glass Ceiling Commission which was to have taken place on Thursday, November 9, 1995 has been rescheduled to Thursday, November 14, 1995.

The purpose of the Commission is to, among other things, focus greater attention on the importance of eliminating artificial barriers to the advancement of minorities and women to management and decisionmaking positions in business. The Commission has the practical task of: (a) Conducting basic research into practices, policies, and manner in which management and decisionmaking positions in business are filled; (b) conducting comparative research of businesses and industries in which minorities and women are promoted or are not promoted; and (c) recommending measures to enhance opportunities for and the elimination of artificial barriers to the advancement of minorities and women to management and decisonmaking positions.

The purpose of this open meeting is to conduct a full Commission vote on the Recommendations Report that will be submitted to the President and Select Committees of Congress.

TIME AND PLACE: The meeting will be held from 2:00 to 3:00 p.m. (EST) in Room C2313 at the Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Individuals with disabilities who wish to attend should contact Ms. Loretta Davis at (202) 219–7342 if special accommodations are needed.

FOR FURTHER INFORMATION CONTACT:

Ms. René Redwood, Executive Director, Glass Ceiling Commission, U.S. Department of Labor, 200 Constitution Avenue, NW., Room C–2313, Washington, DC 20210, (202) 219–7342.

Signed at Washington, DC, this 3rd day of November, 1995.

René A. Redwood,

Executive Director.

[FR Doc. 95–27735 Filed 11–7–95; 8:45 am]

BILLING CODE 4510–23–M